K082322

NOV 14 2008

SECTION 5: 510(K) SUMMARY

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.92.

510(k) Summary	
Date Prepared:	August 12, 2008
Sponsor	Confluent Surgical, Inc. (Covidien) 101A First Avenue Waltham, MA 02451
Contact	Virginia Vetter Phone: (781) 839 1755 Fax: (781) 839 1763 E-mail: Virginia.Vetter@covidien.com
Device Trade/Proprietary Name	Air Assisted Sprayer
Classification Name	Laparoscope, General & Plastic Surgery Class II Product Code: GCJ
Common Name	Air Assisted Sprayer
Predicate Device(s)	MicroMedics Fibrijet Air Assisted Endoscopic Applicator (K042834)
DEVICE DESCRIPTION	
Product Description	The Air Assisted Sprayer Kit consists of multi-lumen tubing that provides separate channels for the flow of two non-homogeneous solutions and filtered pressurized gas.
Indications for Use	The Air Assisted Sprayer is intended to deliver two non-homogenous solutions onto a surgical site.
Safety and Effectiveness	Safety and effectiveness of the Air Assisted Sprayer have been demonstrated in this submission. The biocompatibility and *in vitro* bench testing data provided supports Confluent Surgical's belief that the Air Assisted Sprayer is substantially equivalent to the currently 510(k)-cleared MicroMedics Fibrijet Air Assisted Endoscopic Applicator.
Conclusion	Safety and effectiveness data, same indications for use and same operating principle show the Air Assisted Sprayer to be substantially equivalent to a predicate device under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Covidien
% Ms. Virginia Vetter
Regulatory Affairs Specialist
101A First Avenue
Waltham, Massachusetts 02451

NOV 1 4 2008

Re: K082322
Trade/Device Name: Air Assisted Sprayer
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: November 7, 2008
Received: November 10, 2008

Dear Ms. Vetter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): Unknown K082322

Device Name: Air Assisted Sprayer

Indications for Use: The Air Assisted Sprayer is intended to deliver two non-homogenous solutions onto a surgical site.

Prescription Use __X__ (21 CFR 801 Subpart D) AND/OR Over-the -Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082322